

1 UNITED STATES DISTRICT COURT
2 FOR THE DISTRICT OF NEW JERSEY

3 CIVIL ACTION NUMBER:

4 IN RE: VALSARTAN PRODUCTS
5 LIABILITY LITIGATION

19-md-02875

6 CASE MANAGEMENT CONFERENCE
via ZOOM VIDEOCONFERENCE

7 Mitchell H. Cohen Building & U.S. Courthouse
8 4th & Cooper Streets
Camden, New Jersey 08101
9 July 13, 2022
Commencing at 4:03 p.m.

10 B E F O R E:

THE HONORABLE THOMAS I. VANASKIE (RET.)
11 SPECIAL MASTER

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25 produced by computer-aided transcription.

A P P E A R A N C E S (Continued) :

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ALSO PRESENT:

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Larry MacStravic, Courtroom Deputy

1 (PROCEEDINGS held via Zoom before and SPECIAL MASTER
2 THOMAS I. VANASKIE at 4:03 p.m.)

3 SPECIAL MASTER VANASKIE: All right. I guess we can
4 get started. I don't hear anybody ringing in right now.

5 There it goes. Always happens. I'll wait five
6 minutes and I start talking and it will ring.

7 All right. We have our discovery conference. Looks
8 like it should be a relatively brief conference.

9 And who will be the spokesperson for the plaintiffs
10 on this call?

11 MR. HONIK: Good afternoon, Your Honor, Ruben Honik
12 appearing. You'll be hearing from me as well as
13 Ms. Goldenberg.

14 SPECIAL MASTER VANASKIE: All right. Great. Thanks.
15 Thanks, Mr. Honik.

16 Who will be the spokesperson for the defense?

17 MS. BROWN: Good afternoon, Your Honor. This is Alli
18 Brown for ZHP. I'll be addressing one of the issues, and then
19 my colleague Rich Bernardo will be addressing another. And
20 then I think we have one or two other members of the defense,
21 joint defense group, that will address the third issue.

22 SPECIAL MASTER VANASKIE: All right. Very well.

23 MS. BROWN: And Your Honor, if I could trouble you
24 and everyone else, would it be possible to start with the case
25 management -- the request for the case management order? Only

1 because I'm going to address that, and I'm afraid I can't stay
2 on as long as this may go.

3 SPECIAL MASTER VANASKIE: Yeah, we can address that
4 first.

5 And you're referring to Case Management Order 28?

6 MS. BROWN: Correct, Your Honor.

7 SPECIAL MASTER VANASKIE: Judge Kugler has informed
8 me that he has no problems with respect to that order, and it
9 was my intention to immediately after this conference call
10 send it down to Larry to be docketed --

11 MS. BROWN: Could I be --

12 SPECIAL MASTER VANASKIE: -- unless there was some
13 changes to it.

14 Go ahead.

15 MS. BROWN: Yeah. If I could be heard on that,
16 Judge, that would be terrific.

17 This initial request for the discovery contained in
18 the order came out of a letter that plaintiffs sent us in
19 advance of the June 1st conference in front of Judge Kugler.

20 We had sort of an extensive discussion and argument
21 about just what was being requested. And, you know, Your
22 Honor, one of the things we discussed with Judge Kugler is
23 that we're not necessarily opposed to the concept of
24 discovery. We agree that we need to move these cases forward.
25 We agree discovery in certain circumstances may be needed.

1 The issue and objection that we raised with Judge
2 Kugler was that plaintiffs had not yet at the time of their
3 request identified the case in which they would be seeking
4 this discovery or the state law under which they would be
5 moving for these potential summary judgment motions.

6 And what we did, Judge, in our letter in advance of
7 this conference is we cited to you some of the relevant
8 discussions and statements from Judge Kugler.

9 SPECIAL MASTER VANASKIE: Right.

10 MS. BROWN: And so, for example, if you see there
11 number 2, Judge, our statement on the proposed case management
12 plan, Judge Kugler, I would submit to Your Honor, was
13 unequivocal when he said that the exact claim on which
14 plaintiffs are seeking summary judgment and the statutes under
15 which they're seeking it need to be identified.

16 And when we were discussing this schedule, sort of
17 the very schedule that they're talking about here, I had said,
18 Judge, you know, our position is we need to get to a place
19 where they identify a plaintiff and they identify a state law.

20 And the Judge -- and we cited it here -- said that
21 that was what he intended as well, and that if that didn't
22 happen, he would fix it.

23 And so we would submit to Your Honor, it's not the
24 discovery per se that we are opposing, it's the failure to
25 identify a case.

1 And back in June, the Judge had I believe encouraged
2 the parties to perhaps consider a third-party payor case or
3 consider an individual economic loss plaintiff, but he made
4 clear in response to our objection and argument that he
5 understood the controlling case law that we had reviewed,
6 Judge, that you can't of course move for summary judgment in
7 the ether, that we can't move on liability issues untethered
8 to particular claims, to particular plaintiffs, and
9 importantly for the Court, to a particular law.

10 And I think the Judge was very clear here that he
11 believed the proposal contemplated the identification of a
12 plaintiff and the identification of the law and that that
13 would have to be done to frankly give us our due process
14 rights to be able to request our own discovery and to be able
15 to properly respond to any motions that plaintiffs might file.

16 So our objection, Judge, is to the form of the order,
17 which respectfully is no different than the letter that we
18 argued in front of Judge Kugler and which Judge Kugler made
19 clear did not sufficiently identify plaintiffs or the state
20 law.

21 SPECIAL MASTER VANASKIE: What exactly are you
22 proposing, Alli?

23 MS. BROWN: Sure. Thanks, Judge.

24 So what I understood coming out of our discussion and
25 coming out of the Court's direction was that plaintiffs were

1 to let us know the identity of a plaintiff, you know, the
2 case, the named plaintiff and the case, in which they wanted
3 this discovery, first and foremost so that we would know what
4 claims are at issue; importantly for the Court, what law is
5 applicable. And as I understood Judge Kugler, because the
6 case -- the class certification motions are still pending, he
7 was indicating that perhaps the parties wanted to think about
8 a third-party payor class.

9 We had suggested -- and Judge, to be quite candid, I
10 know Judge Kugler has rejected it, but we had suggested
11 discovery in the context of personal injury plaintiffs. I
12 understand that's not where the Court wants to go.

13 But coming out of the conference, and certainly we
14 cited it here, what was clear is that he expected, and
15 frankly, controlling law would demand it, that we have the
16 identify of the case and the plaintiff and the law at issue
17 and the claims under which they intend to move.

18 And if you look at the transcript and the parts we
19 cited here, I think that squares perfectly with what the Judge
20 said would happen, and if it doesn't, we'll fix it.

21 And so I guess we're just coming to you, Judge, to
22 say, I think this case management order needs a little fixing
23 along the lines of what Judge Kugler talked about on the 1st.

24 MR. HONIK: Your Honor, may I address it? I think I
25 can resolve the issue that Ms. Brown is bringing up.

1 SPECIAL MASTER VANASKIE: You certainly may,
2 Mr. Honik.

3 MR. HONIK: So let me provide a tiny bit of context.

4 It's correct that this issue came up just exactly as
5 Ms. Brown is setting out. And we have had a number of meet
6 and conferrals about this, and I think we better understand at
7 this point the issue that the defendants have raised. And
8 they're not incorrect.

9 And so what we are proposing, and in fact what we
10 will be doing, by no later than the beginning of next week, to
11 Ms. Brown's point and request, we will be identifying with
12 specificity the economic class group or subgroup that we
13 intend to pursue dispositive motions on and identify the
14 plaintiffs or class representatives that relate thereto. And
15 in fact, we intend to lay that out in our next letter to the
16 Court so that we can present it to Judge Kugler and actually
17 attach a trial plan. Because after all, what this case
18 management order is about, is simply moving the case forward.

19 Now, ordinarily, you know, we might have a certain
20 sequence of events. We might have had or may be nearer a cert
21 ruling which may help inform and narrow the issues and so
22 forth. But in the absence of that, I think the case
23 management order as we have proposed it to the Court and
24 discussed at our last conference, which Judge Kugler is
25 prepared to enter, is perfectly fine in its current form,

1 coupled with the representation we're now making on behalf of
2 the plaintiffs' group, that Ms. Brown and the defendants will
3 have by next week exactly what they have been seeking, which
4 is the identity of one or more class groupings, the class reps
5 who are there, the defendants, in fact, that we propose to
6 pursue against with respect to dispositive motions, and
7 therefore, address all of the issues that Ms. Brown has
8 brought up.

9 SPECIAL MASTER VANASKIE: All right. Ms. Brown, why
10 don't we proceed on that basis?

11 Go ahead.

12 MS. BROWN: Your Honor, thank you very much.

13 And I appreciate the clarification from counsel.
14 What I would suggest in that instance, Your Honor, is that we
15 not put the cart before the horse here and that we wait to get
16 counsel's representations of the plaintiffs and the law and
17 the claims.

18 And the reason I say that, Judge, is because counsel
19 said a couple of things that made me nervous in terms of
20 controlling law.

21 He made some references to class plaintiffs. And of
22 course I don't have to tell Your Honor, the law would prevent
23 this Court from making any rulings on a putative class that
24 has not yet been certified.

25 And so I think the proper way to go about this,

1 truthfully, to allow us to properly assess what it is that
2 they're proposing, if we can hold off a week, if we can get
3 the information from counsel, have the opportunity to meet and
4 confer with them on just what their proposal is, and then
5 either come back to you or Judge Kugler if there remains any
6 objections.

7 And I think there might, based on the little bit of
8 information I just heard. But at this point it's really hard
9 to assess that without that information, Your Honor.

10 MR. HONIK: Your Honor, I'm at a loss to really
11 understand.

12 The Case Management Order Number 28 that we've
13 proposed really simply addresses the exchange of expert
14 reports on merits and dispositive motions, putting that on the
15 calendar.

16 We control our case. We're the plaintiffs. And we
17 will identify those areas and those motions that we intend to
18 file. It doesn't impact putting this on the calendar. And
19 unless Ms. Brown can enlighten the Court and myself and the
20 rest of the plaintiffs precisely how learning who we choose to
21 file or what we choose to file dispositive motions about
22 impacts putting these dates on the calendar, I'm at a loss to
23 understand why Judge Kugler doesn't do what he, I think, is
24 poised to do, which is to enter this order today so that we
25 have it on the calendar and all of us can benefit from knowing

1 when these various important dates are going to come up.

2 MS. BROWN: Judge, if I may, I think I could answer
3 that question, if the Court would allow me.

4 SPECIAL MASTER VANASKIE: Go ahead.

5 MS. BROWN: Okay. Your Honor, the reason we need to
6 know the plaintiffs and the case and the claims is because we
7 too will seek certain discovery. And the Judge made that
8 clear last time, that this was not going to be a one-way
9 street, where only plaintiffs can pursue discovery, but
10 certainly defendants in defending these cases and in
11 exercising our due process rights would have the ability to
12 have our own discovery.

13 And so just take, for instance, we started to look at
14 the third-party payor cases, as the Judge sort of encouraged
15 us to do. And there's a host of discovery, Your Honor, that
16 we would need -- and frankly, we raised this with counsel on a
17 meet and confer -- that we would need in some of those cases,
18 to be able to respond, to have responsive expert reports, to
19 be able to defend against those motions.

20 And so before we put a schedule in place that we have
21 no idea what the plaintiff is, we have no idea what the law
22 is, we need to know that information so that we can propose
23 our own part of this case management order that would allow
24 for the very same equal discovery that Judge Kugler indicated
25 was appropriate on our last conference.

1 MR. HONIK: Your Honor, I'm --

2 SPECIAL MASTER VANASKIE: Let me ask a question,
3 please, Mr. Honik. All right?

4 MR. HONIK: Sure.

5 SPECIAL MASTER VANASKIE: You were going to answer it
6 with what you were about to say, so we'll see. We'll see if
7 we're on the same wavelength.

8 But what would be inappropriate -- and I'm asking
9 this question of Ms. Brown now.

10 What would be inappropriate about entering this order
11 and then taking up at our next case management conference some
12 of these matters that you've talked about in terms of fleshing
13 out the order? In other words, this is the skeleton. Now
14 we're going to hang some skin on the skeleton, put some muscle
15 on it, et cetera, to flesh it out. Bad analogies. But what
16 I'm trying to indicate is we have a framework here that sets
17 up a schedule, and then we can fill in that framework.

18 What would be wrong with that?

19 MS. BROWN: Well, Your Honor, I believe that was the
20 very subject of the argument in front of Judge Kugler in early
21 June, because the schedule that they've submitted here for
22 signature and entry is the very proposal that was the issue in
23 front of Judge Kugler. It's the very proposal we objected to,
24 because frankly, it's contrary to law, to allow this type of
25 expert liability, expert discovery, liability, Daubert

1 motions. It contravenes controlling law which says you can't
2 address liability in the ether without a complete cause of
3 action, without the causation and the damages.

4 And we made the argument and we cited the cases to
5 Judge Kugler who agreed. And he, you know, was quite clear on
6 the record, that is not what was going to be done here. We
7 were not going to have what's being asked for in this case
8 management order.

9 And so I would submit the proper way to proceed is to
10 at least allow us the opportunity to understand what Judge
11 Kugler said the plaintiffs would provide us with, which is the
12 plaintiff, the state, the claims, give us an opportunity to
13 just have that information, and then we can meet and confer on
14 what we believe would be a proposed -- an appropriate
15 schedule.

16 But my objection, Judge, is that the proposed order
17 was the subject of the hearing in front of Judge Kugler, and
18 Judge Kugler said that plaintiffs would have to identify
19 plaintiffs and law before we could proceed.

20 MR. HONIK: Respectfully, Your Honor, the Judge did
21 not say that that was a requirement before imposing a
22 schedule. And no one is proposing that there should be a
23 summary judgment ruling or I dare say a trial on the merits
24 before certification. No one is proposing that at all. But
25 what we're trying to do is to honor what the Court has asked

1 us to do, which is to move the case forward.

2 Class cert is fully briefed. Whenever the Court
3 should deign to rule on that, that's fine. But we took Judge
4 Kugler at his word that he wants to try to move the case to
5 conclusion or near conclusion to the calendar year -- to the
6 end of the calendar year.

7 To that end, we proposed this order. It really
8 doesn't in and of itself contemplate discovery beyond the
9 exchange of expert reports. And I would point out the
10 obvious: That discovery in the strict sense has been closed.
11 I'm at a loss to understand what discovery Ms. Brown is really
12 contemplating.

13 So let me conquertize this. We know that the first
14 trial, if you will, or disposition of cases are going to be in
15 the economic track, not the bodily injury track. So if we
16 take, for example, some grouping of defendants, say ZHP, and
17 we know that one of the claims we briefed on certification and
18 we intend to proceed on on liability is express warranty.

19 I would ask Ms. Brown what conceivable discovery do
20 you need to move on that?

21 We're going to file a motion for summary judgment on
22 that. We're going to believe there's both a factual and legal
23 record upon which the Court can narrow the issues so that we
24 can move forward with the trial of the case, subject, of
25 course, to a cert ruling.

1 So what this order does is simply commit that to the
2 calendar. And there's no prejudice or harm to Ms. Brown and
3 the defendants by the Court entering this order. And if
4 indeed there's some problem that I don't see today, it can be
5 brought up to Judge Kugler, you know, at the end of the month.
6 And if by some chance there needs to be a modification or
7 addition to this order, we can always have another one.

8 But it's now been several weeks since the Judge ruled
9 that this order should go in plus 60 days, and we would simply
10 respectfully request it be entered today without prejudice to
11 Ms. Brown and the defendants to raise any other issues which
12 really don't appear to be very concrete today.

13 MS. BROWN: Your Honor, I believe the prejudice is
14 enormous. I believe this is contrary to controlling law and
15 would deprive us of our due process rights. I believe this
16 order was the very order that was the subject of argument on
17 June 1st, and I think the Judge was clear, and we cited the
18 pages here, that they need to identify for us the state law.
19 Counsel says he wants to move under express warranty.

20 What state law is going to control that, and what
21 plaintiff is at issue?

22 And it sounds like counsel has in mind certain cases,
23 certain laws, certain claims, Your Honor. And we would just
24 respectfully request the opportunity to meet and confer on
25 those and to understand what the cases are so that we too can

1 propose our own discovery that would be needed rather than a
2 case management order that I would respectfully submit has
3 already been discussed and Judge Kugler pointed out the
4 deficiencies.

5 SPECIAL MASTER VANASKIE: All right. I'm going to
6 issue this order. I'm going to sign the order that has been
7 presented. I think, as I said before, you can fill in the
8 details of this order.

9 Mr. Honik, you're going to be providing some
10 additional information with respect to what the claims and
11 under what state law you believe you will be moving, so you'll
12 be providing that notice.

13 The order itself calls for dispositive motion --
14 deadline for dispositive motions in December of 2022. There's
15 plenty of time to provide adequate notice with respect to what
16 those claims are. Discovery is supposed to have been closed
17 except for expert witness discovery. If there's a need to
18 reopen it, that can be revisited upon the appropriate request.

19 MS. BROWN: And Your Honor, the --

20 SPECIAL MASTER VANASKIE: And I think it is important
21 that this matter move forward with a schedule in mind. And I
22 think this order accomplishes that.

23 Go ahead, Ms. Brown.

24 MS. BROWN: Thank you, Judge. I didn't mean to
25 interrupt.

1 Could we just request that we identify a date by
2 which they'll give us the information that it sounds like
3 counsel has in mind.

4 MR. HONIK: Yeah. By the middle of next week, Your
5 Honor.

6 SPECIAL MASTER VANASKIE: Okay. So today is the
7 13th. So we'll say by July 20th.

8 MR. HONIK: That's fine. Thank you, Your Honor.

9 SPECIAL MASTER VANASKIE: All right.

10 MS. BROWN: Thank you, Your Honor.

11 And with your permission, Your Honor, I'll hand the
12 rest over to my colleagues, and if I could be excused.

13 SPECIAL MASTER VANASKIE: You may be excused. Thank
14 you, Ms. Brown.

15 MS. BROWN: Thank you very much, Judge.

16 SPECIAL MASTER VANASKIE: Thanks.

17 The next issue I believe that should be taken up then
18 is the question of the scope of core discovery for the
19 losartan and irbesartan matters.

20 And are you addressing this, Mr. Honik?

21 MR. HONIK: I'm going to pass it off to Ms.
22 Goldenberg, Your Honor.

23 SPECIAL MASTER VANASKIE: Okay, good.

24 Ms. Goldenberg?

25 MS. GOLDENBERG: Hi, Your Honor.

1 The good news is we only have a couple of very small
2 issues for you. We had a couple of productive meet and
3 confers leading up to this. And the starting point was the
4 core discovery of course has already happened once. We don't
5 need to relitigate all of the issues. And so we have agreed
6 that all of the previous rulings on core discovery are, you
7 know, very instructive as to where we go from here.

8 And really, the big issue that we need to talk with
9 you about today is whether or to what extent defendants need
10 to turn over testing results for nitrosamines in their pills.

11 In our mind -- you know, we've been in this court
12 many times. We've been here for a few years already. And it
13 seems like it's probably not a surprise that we would want
14 testing levels for the pills that we haven't gotten testing
15 results for yet.

16 And we did make it clear to defendants that when we
17 saying testing results, we're not asking for all of the raw
18 chromatography data yet, what we really want are the numbers.
19 So what we want to know is how many nanograms or parts per
20 million of nitrosamines are in these pills. And we have
21 prioritized that with the understanding that the Court has
22 ordered us to get our claims in order and to figure out what
23 our priorities are.

24 So that's the ask. And I think I'll stop there for
25 now.

1 SPECIAL MASTER VANASKIE: Okay.

2 And who is addressing this issue for the defense?

3 MR. BERNARDO: I am, Your Honor, Rich Bernardo.

4 SPECIAL MASTER VANASKIE: All right. Thanks,
5 Mr. Bernardo.

6 MR. BERNARDO: And I appreciate Ms. Goldenberg's
7 comments, and I agree. We've had a couple of successful meet
8 and confers.

9 But I want to take a step back, because what might
10 seem to be simple from Ms. Goldenberg's description really is
11 anything but simple, and it's very burdensome, and we're just
12 trying to put some reasonable parameters on it.

13 So just to sort of take a step back and recall, Your
14 Honor, the purpose of core discovery -- and I'm just using the
15 phraseology that was in the order back in '19 on core
16 discovery -- talked about easily identifiable, relatively
17 simple to retrieve and discrete. And the core discovery had
18 certain parameters to it. And those were all spelled out in
19 an order back in 2019.

20 When plaintiffs presented the core discovery for
21 irbesartan and losartan, they added to that. And they added
22 in a couple of material respects. They added something that
23 just said all nitrosamine testing. They added additional
24 production of FDA materials. And during the meet and confer,
25 they further added to sales data.

1 Defendants are trying to be cooperative and come to
2 some reasonable compromise here and agreed with respect to
3 getting reasonably available sales data, agreed to providing
4 additional FDA materials.

5 And I point out, Your Honor, that those were
6 materials that I understand took substantial time to pull
7 together and were done in terms of general discovery last
8 time, but we agreed to do that.

9 We even agreed to say we will provide some amount of
10 nitrosamine testing material, mindful of the fact that the
11 defendants who have participated in discovery already provided
12 anything pre-recall as part of the Court's order. But we
13 pointed out that the nitrosamine testing was a significant
14 burden in the valsartan period and took many, many months. It
15 was the subject of -- and I think we spelled them out in our
16 letter -- like two dozen different requests.

17 And I can't speak for the specific details of the
18 burden for each defendant, but I can describe for Your Honor
19 that it's not a push button, for example, for my clients. I
20 spent time with them, and I understand it's something that
21 literally needs to be manually compiled through hard copy
22 material in correlation with data analyses they have.

23 Again, if it were something super easy, we wouldn't
24 put up a philosophical blockade, but it isn't. It's something
25 that's very, very detailed. And what we proposed to do as

1 just a compromise was to provide the nitrosamine testing for
2 irbesartan and losartan as an initial offering that was
3 provided to FDA. That certainly should be ample to provide
4 plaintiffs the core type of information that they need, but we
5 don't agree at this point in time going beyond that.

6 Plaintiffs in their letter say, well, you should have
7 known this was coming. But actually, we shouldn't, because I
8 think Judge Schneider was very, very specific in his prior
9 rulings that discovery was about valsartan, in fact even made
10 comments I saw in the transcript that he didn't think
11 discovery in losartan and irbesartan would materially advance
12 anything given the volume of what was produced on valsartan.

13 So, again, trying to be reasonable, trying to
14 accommodate but needs some reasonable limits, because I will
15 represent certainly not for ZHP -- and I've been told by my
16 colleagues and the co-defendants, not for them either -- can
17 they do what plaintiffs are asking for in 90 days. And it
18 would require a significant burden.

19 SPECIAL MASTER VANASKIE: All right. Ms. Goldenberg?

20 MS. GOLDENBERG: Just a quick response to that, Your
21 Honor.

22 I'm very glad that Mr. Bernardo brought up that this
23 was the subject of multiple discovery requests, because, yes,
24 we asked for it before, and I don't think it's a surprise that
25 we were going to ask for it this time, so I don't think it was

1 a surprise that they -- that we would want the testing data.
2 This is the core of all of the claims. And as plaintiffs'
3 leadership, we've, you know, been tasked with the duty of
4 working up these cases as to all three drugs. The fact that
5 discovery was going to be coming and that we might need this
6 information in order to ultimately resolve this MDL should not
7 be a surprise to anyone.

8 And while core discovery at the beginning of this
9 litigation was designed to be the easily accessible documents
10 because everyone had just started, we've been here for almost
11 three years now. And it is shocking I think on our side to
12 think that the defendants wouldn't have figured out what their
13 testing results were for these other two drugs that have been
14 a part of this MDL for a long time now.

15 But as to how to retrieve it, again, it's wonderful
16 that the defendants raised the RFPs, because they've already
17 put together search methodologies to retrieve testing results
18 in the past, and we anticipate that those same methodologies
19 could be utilized here again.

20 And so we -- this is some of the most important
21 information we could have in this case. It seems very
22 difficult to believe that they couldn't produce this to us.

23 SPECIAL MASTER VANASKIE: Why --

24 MR. BERNARDO: I -- I'm sorry, Your Honor.

25 SPECIAL MASTER VANASKIE: Why isn't the production of

1 the testing data provided to the FDA sufficient, at least
2 for -- at least initially?

3 MS. GOLDENBERG: We have already seen some different
4 data come in from lower tier defendants in this case that
5 differs from the testing -- the limited testing data that we
6 have from the defendants on the losartan and irbesartan. And
7 it's our understanding that there is a lot more that we don't
8 have that wasn't turned over to the FDA.

9 We also found out at the beginning -- or sorry, in
10 the valsartan portion of the case that there were testing data
11 levels that materially differed from what was turned over to
12 the FDA. And so now that we understand that those differences
13 exist, we can't rely on what was turned over to the FDA.

14 MR. BERNARDO: And Your Honor, may I address two
15 points that Ms. --

16 SPECIAL MASTER VANASKIE: You may.

17 MR. BERNARDO: Thank you, Your Honor.

18 I want to be clear, I'm not standing here, saying
19 we're shocked that you're interested in nitrosamine testing,
20 or, you know, that we haven't engaged in methodologies to
21 identify that testing for valsartan that we can use here.
22 What I'm saying is that what we're talking about here is core
23 discovery, easily identifiable, relatively simple to retrieve
24 and discrete.

25 Nitrosamine testing was never part of core discovery

1 for that very reason. And what I'm just describing is looking
2 at the methodology that would need to be applied to losartan
3 and irbesartan.

4 And this is for those defendants who already had
5 engaged in discovery on valsartan. I want to remind the Court
6 that there are defendants who would be responding to this who
7 didn't do that. It's not something that can be done in a
8 simple or short time frame, and it's not necessary for an
9 immediate -- again, not saying never, not even saying, you
10 know, when it would be, just saying not something to request
11 within 90 days.

12 MS. GOLDENBERG: Your Honor, if I could just --

13 SPECIAL MASTER VANASKIE: Go ahead. Sure, Ms.
14 Goldenberg.

15 MS. GOLDENBERG: I should also mention that the
16 testing turned over to the FDA oftentimes was just about
17 limited batches of losartan or irbesartan or, in the previous
18 portion of the case, valsartan.

19 We have defendants in this MDL who did not recall all
20 of their pills on the basis that they say not all of them were
21 contaminated. And so when we are trying to evaluate the level
22 of liability that might be assigned to a particular defendant
23 in this case if what we have at the beginning is only limited
24 testing data, it's not going to tell the full story.

25 SPECIAL MASTER VANASKIE: Is it correct that

1 nitrosamine testing results were not part of core discovery
2 for valsartan?

3 MS. GOLDENBERG: It is correct, Your Honor.

4 MR. HONIK: Your Honor, may I add one thing just as a
5 practical matter, which is not --

6 SPECIAL MASTER VANASKIE: Certainly, Mr. Honik.

7 MR. HONIK: I'm very mindful, and it's the remaining
8 issue for today's conference, that we've been court ordered to
9 mediation.

10 It's unimaginable to me that these defendants if they
11 proceed, as I'm sure they will, in good faith to mediate with
12 us, that they're going to want to mediate less than a global
13 resolution of all claims.

14 I don't really know as a practical matter how a month
15 from now we go into mediation without understanding what the
16 levels of contamination were in losartan and irbesartan.

17 And so if for no other reason than that, it
18 seems to me critical to obtain that kind of core discovery,
19 because what we're going to hear invariably is, well, we don't
20 want to pay you X because our contamination was Y, or it
21 didn't cover all pills, or what have you.

22 And in order for us to have a meaningful engagement,
23 which I think the Court wants us to have, in understanding, as
24 this MDL is about, all three, you know, drugs here, we really
25 need to get our arms around what these levels were.

1 And so in many respects, we tailor our request with
2 that in mind. And it's eminently reasonable, and recognizing
3 as we do three years into this litigation the sometimes
4 disparate results between what the FDA has and what the
5 companies themselves have, it strikes me as eminently
6 reasonable for them, that is, the defendants, to produce it.

7 If the issue is one of execution and they need more
8 time or they need to do it on a rolling basis, we can
9 certainly address that. We don't want to impose unfairly or
10 unduly. But it seems to me seminal to advancing this case and
11 being appropriately prepared for mediation, as I'm sure the
12 Court wants us to be, to have these values.

13 MR. BERNARDO: Your Honor, and I appreciate
14 Mr. Honik's comments, and I don't want to mince words. And to
15 be clear, we here on this call for defendants and for
16 plaintiffs are not part of this conference in late August.
17 There are separate settlement counsel, as I'm sure Your Honor
18 is aware.

19 SPECIAL MASTER VANASKIE: Right.

20 MR. BERNARDO: As I understand it, it is not a
21 mediation, but again, I don't want to mince words, it is a
22 settlement conference that was ordered.

23 But I reached out to our settlement counsel, and I
24 asked my co-defendants who are participant as well to reach
25 out to theirs, just to get a better understanding of this and

1 what plaintiffs are asking for here.

2 And what I heard from all of these folks through my
3 colleagues, some of which are on this call, they're confused
4 and they're not aware of any reason why the type of
5 information that plaintiffs are seeking to accelerate here,
6 particularly for an August conference that I understand is an
7 initial conference, is really relevant and in fact thought at
8 some level it could end up, you know, taking away the proper
9 focus.

10 Having said all of that, a rolling basis and starting
11 some in 30 days doesn't really help what I understand is the
12 burden and the amount of time.

13 I mean, this took many, many, many months for
14 valsartan to be produced. We are in the middle of the summer,
15 when, as I'm sure Your Honor appreciates, many people,
16 including the contacts that many of us would have at our
17 clients to try and even begin to get this stuff, are
18 unavailable for periods.

19 So again, I'm not -- I'm not disagreeing with
20 providing this information. I'm sort of going back to your
21 question, which is, is this part of core discovery, was it
22 part of core discovery, and the answer is no. And if it is,
23 we're willing to agree to some reasonable limitation.

24 We proposed what was provided to FDA. We got nothing
25 back as an alternative. What we got back is literally the

1 words "all nitrosamine testing."

2 I'm not even sure I fully understand what that means.
3 You know, any testing for all release testing done through,
4 like, yesterday? So it's just -- it's the definition of an
5 overly broad request that's at this point a fishing
6 expedition. And it really can't be part of the core
7 discovery, particularly while we're also trying to pull the
8 other materials that are, we agree, part of core discovery and
9 do those on a rolling basis in a methodical manner.

10 MR. HONIK: Judge Vanaskie, I know that you were not
11 our master the entire duration of the litigation, but my
12 memory is very clear that most, really all the defendants but
13 one, got this material to us exceedingly promptly. We're not
14 asking them to do testing now. This is testing that was
15 already done that revealed levels which is stored somewhere.

16 The one and only defendant who took months to produce
17 this did so because they decided to ship empty hard drives
18 from India rather than do it from their computers. And I know
19 Your Honor remembers that.

20 So, you know, just to be clear, I'm really at a loss
21 to understand why it would take months. This information must
22 exist somewhere in the defendants' current possession. And
23 gathering that in some electronic way and sharing it with us
24 so that we can meaningfully have this information, it's
25 clearly relevant, and I say it's directly relevant to

1 evaluating the case. Whether next month is a settlement
2 conference or a mediation, we're three-and-a-half years into
3 the case, we just want the information. We think it's
4 reasonable that we should have it now.

5 SPECIAL MASTER VANASKIE: Well, I understand that.
6 But even under the core discovery order, there's no assurance
7 you'll have it within -- before the end of August.

8 MS. GOLDENBERG: Your Honor, I can --

9 SPECIAL MASTER VANASKIE: You can do a rolling
10 production --

11 Go ahead, I'm sorry.

12 MS. GOLDENBERG: Oh, I was going to say, Your Honor,
13 we actually offered to defendants to prioritize our requests,
14 because we recognized that there may be some issues in
15 producing everything at once. So we had told them that the
16 most important pieces of information for us were these
17 nitrosamine testing levels and the sales data.

18 I understand that what I'm about to hear in response
19 is that this is the most difficult thing to produce.

20 And obviously, you've heard already from us that we
21 disagree with that for the reasons we've already articulated,
22 but we have made an effort to prioritize our requests, because
23 this is, as Mr. Honik already articulated, for mediation the
24 most important piece of information that we can have.

25 MR. BERNARDO: Your Honor, I wouldn't be up here

1 making this argument, and at the risk of beating a dead horse,
2 if this were pushing a button and easy to produce. And it's
3 very easy for plaintiffs who don't have access to our client
4 or their systems to say what is or isn't easy.

5 I can also represent my understanding, and I actually
6 had a call with my clients two nights ago to go through this,
7 because this was not a quick process for ZHP and took many,
8 many months. I'm not sure what Mr. Honik is referring to in
9 India. I suspect that's not ZHP. But I'm telling you that it
10 was a lengthy process. And I don't know if Steve -- I don't
11 see his name, I think he's on -- Harkins, you know, who lived
12 through this or Victoria can confirm that, but it wasn't a
13 quick process.

14 SPECIAL MASTER VANASKIE: Well, I understand it may
15 not be a quick process, and it's not pushing a button and
16 taking a printout, providing it or downloading it or sending
17 it as a digital file, but it is essential to the case. The
18 fact that it wasn't part of core discovery initially to me
19 isn't critical. I believe ultimately it's going to have to be
20 produced, and I think it would be appropriate to make it part
21 of core discovery.

22 So I will require the production of the nitrosamine
23 testing results. We're talking only about the results, not
24 the underlying chromatograms, I take it. So I'll require
25 that.

1 If you need additional time beyond the 90 days and
2 can demonstrate why you need more than 90 days, certainly I'd
3 be sympathetic towards it.

4 But let's make it part of core discovery, not a
5 subset. A subset of it was already going to be a part of core
6 discovery as a result of your meet and confers.

7 And I want to acknowledge and express certainly my
8 understanding and appreciation of your efforts to work out
9 agreements on these matters. And so you reached an agreement
10 that at least the FDA, the results that went to the FDA would
11 be produced, but I'm going to expand it beyond that, because
12 ultimately it's going to have to be produced. And so --

13 And it does seem within -- it may not be easily
14 retrievable, it may not be low-hanging fruit, but it is core.
15 And I think efforts should be undertaken now to produce that
16 data. So I will require that it be produced as part of the
17 core discovery order.

18 MR. BERNARDO: May I ask -- thank you, Your Honor --
19 two follow-up items on that --

20 SPECIAL MASTER VANASKIE: Sure.

21 MR. BERNARDO: -- that are part of plaintiffs'
22 letter.

23 As I'm hearing Your Honor, if it does become
24 burdensome to pull all this together and get it out within 90
25 days, we can come back, raise our hands, maybe come back to

1 Your Honor.

2 Plaintiffs have asked for this to be produced within
3 30 days, and I can represent at least for my client -- and I'm
4 sure others would have the same thing -- it cannot be produced
5 within 30 days. We'll make efforts to prioritize it as Your
6 Honor has requested.

7 And then the other piece of that is that there's some
8 request in here, I forget what it was, to have a rolling
9 production, be a weekly production.

10 Your Honor, that becomes actually counterproductive.
11 Without getting into the details of how the vendors work and
12 how you have to lock down things, doing something on a weekly
13 basis is going to make it slower.

14 I mean, I don't see any need for any requirement of
15 the interim period of production, but if something is
16 required, maybe like a monthly or something like that would be
17 appropriate. But to request a weekly is not how it's ever
18 done in litigation like this for the very good reason that it
19 becomes more time-consuming and more burdensome than trying to
20 do it on some longer period of time.

21 We recognize -- and Ms. Goldenberg and I discussed
22 this. We're not intending a rolling production to be, you
23 know, a page in July, a page in August, and, you know, 20,000
24 pages in September. We understand that. But I don't think we
25 need some management of what rolling means.

1 SPECIAL MASTER VANASKIE: All right. All right.
2 That's understood. I would not require weekly rolling
3 production. I will not require that all this testing data be
4 produced within 30 days, but it will be part of the core
5 discovery order.

6 I know, Ms. Goldenberg, this may not be timely
7 insofar as the settlement conferences are concerned, but my
8 experience with matters of this magnitude is that won't be the
9 only settlement conference that is conducted. It will take
10 some time.

11 And so the defense can get moving and producing this
12 data, and it will be done within the parameters of the core
13 discovery order. All right.

14 MS. GOLDENBERG: Understood, Your Honor.

15 One other issue that was mentioned in the letter, and
16 it is just a small one and I don't think necessarily a matter
17 for dispute, but we need to -- in an effort to be targeted,
18 understand the relevant time period for each defendant so that
19 we can focus our efforts. And we're just asking the Court to
20 order the defendants to disclose to us what they view to be
21 the contamination period within a week's time so that we can
22 evaluate that based on the information we have and move
23 forward accordingly.

24 MR. BERNARDO: Thank you for raising that, Marlene.
25 I should have raised that as well. It was on my list.

1 But I think we're having a disconnect, Marlene and
2 Your Honor. The contamination period was never something the
3 defendants agreed would be the relevant period for discovery.

4 And what we did, and we provided a proposed order, we
5 suggested that we abide by what Judge Schneider did, the
6 process, which, as I understand it, was essentially the
7 manufacturing period plus one, in other words, going back one
8 year farther.

9 And while the defendants, you know, can certainly
10 provide what that is, I don't know that doing it within a week
11 is necessarily doable for everybody. It may be for ZHP, but
12 it may not be for others, to sort of pin that down.

13 I suggest -- this isn't going to hold anything up.
14 Nobody's going to, like, not do things while they're sorting
15 that out. What I suggest is that the defendants provide that
16 to Ms. Goldenberg. And if there are any disputes, we'll just
17 make sure, like we did last time, they get resolved in advance
18 of the next conference, or if they can't be resolved, they get
19 addressed with Your Honor.

20 I don't see this as being a significant issue, but I
21 just wanted to point out that we're not talking about the,
22 quote/unquote, contamination period. I mean, that's an issue
23 in the case. Right? What we're talking about is the period
24 for relevant discovery. And we suggested that we do it the
25 same way we did it for valsartan, which is spelled out in the

1 Macro Discovery Order 303 and the transcript that led to that,
2 which is Document 302.

3 MS. GOLDENBERG: And as long as what you're referring
4 to is the manufacturing period, meaning the entire time the
5 product was manufactured, minus one year, I think we're fine.

6 MR. BERNARDO: Yeah. And again, I want to be
7 careful, Marlene, not to speak for all the defendants. I
8 mean, I know from ZHP's perspective and I know from others',
9 that's fine. If other defendants have some unique issue,
10 they'll raise their hand and let you know. But for ZHP and I
11 know for some other defendants, we're fine doing it that way.

12 MR. HONIK: And for the record, it's the
13 manufacturing period plus a year --

14 MR. BERNARDO: Right.

15 MR. HONIK: -- not minus a year.

16 MS. GOLDENBERG: Sorry, yes.

17 MR. BERNARDO: I'm sorry, I thought I said plus and
18 Marlene said minus.

19 MR. HONIK: It's plus.

20 MR. BERNARDO: Yes. Agree.

21 MS. GOLDENBERG: Back in time. We agree.

22 MS. BERNARDO: One year prior, how about that?

23 SPECIAL MASTER VANASKIE: Right.

24 Now, do I have in a document submitted from
25 plaintiffs a proposed core discovery order?

1 MS. GOLDENBERG: We will be happy to codify what was
2 submitted to you -- I apologize, I heard an echo.

3 We will be happy to modify what was submitted based
4 upon your rulings today and submit it to you.

5 SPECIAL MASTER VANASKIE: All right. Very well.

6 MR. BERNARDO: Marlene, I think that just is
7 essentially tinkering with the nitrosamine testing. Correct?

8 MS. GOLDENBERG: I think that's right.

9 SPECIAL MASTER VANASKIE: I think that's right as
10 well.

11 All right. Anything else for today?

12 I think there was something with respect to the
13 settlement conferences or the mediation session.

14 Who will be addressing that?

15 MR. HONIK: Yes, Your Honor. We raised an issue
16 pertaining to that.

17 The order directing the settlement conferences, the
18 first of the two directs defendants ZHP, Mylan, Hetero,
19 Aurobindo and their subsidiaries and affiliates to attend.

20 And to be sure, the way we've been thinking about
21 these cases, Teva and Torrent is an affiliate and belongs
22 there, in no small part because they used the API from ZHP.
23 In Teva's case I think they also purchased Mylan API. But
24 that's the groupings. Those are the manufacturers the way
25 we've constructed and think about the case. And we just

1 wanted to clarify that both Teva and Torrent are invited to
2 the first dance.

3 SPECIAL MASTER VANASKIE: And this matter was brought
4 to Judge Kugler's attention. And it's my understanding that
5 he's referred the issue to the settlement masters for their
6 determination and leaving it up to them whether to include
7 them at the -- invite them to the dance.

8 THE LAW CLERK: Judge Vanaskie, may I address that?

9 SPECIAL MASTER VANASKIE: Yes, Loretta.

10 THE LAW CLERK: Judge Kugler heard from the
11 settlement masters last evening, and they are -- they have
12 proposed not to include the finish dose manufacturers in this
13 first settlement conference.

14 SPECIAL MASTER VANASKIE: All right.

15 THE LAW CLERK: Just to go forward with the API
16 manufacturers as listed in the order.

17 MR. HONIK: Thank you for that clarification.

18 SPECIAL MASTER VANASKIE: Okay. Thanks, Loretta.

19 THE LAW CLERK: Sure.

20 SPECIAL MASTER VANASKIE: All right. Is there
21 anything else then for today?

22 MR. HONIK: Nothing for plaintiffs, Your Honor.
23 Thanks.

24 MR. STOY: Judge Vanaskie, very briefly, this is just
25 Frank Stoy for Mylan and the defense group.

1 I just wanted to remind the Court that we do have a
2 motion still pending related to some testing results for one
3 of plaintiffs' experts, Dr. Najafi. We just wanted to make
4 sure that hadn't sort of slipped through the cracks, so I just
5 offer that PSA to the Court.

6 SPECIAL MASTER VANASKIE: All right. I thank you for
7 the PSA. And we'll get moving on that.

8 Is there anything else then?

9 All right. We will issue CMO, Case Management Order,
10 28. I'll await receipt of a revised core discovery order that
11 can be issued. And we'll see you all or talk to you all in a
12 couple of weeks, I suppose okay.

13 RESPONSE: Thank you, Your Honor.

14 SPECIAL MASTER VANASKIE: Thank you all very much.
15 Thanks. Bye-bye.

16 (Proceedings concluded at 4:51 p.m.)

17 - - -

18 I certify that the foregoing is a correct transcript
19 from the record of proceedings in the above-entitled matter.

20

21 /S/ Ann Marie Mitchell, CCR, CRR, RDR, RMR
22 Court Reporter/Transcriber

23

24 15th day of July, 2022
25 Date

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